MAY 3 1 2002

K020802

510 (k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BAUSCH & LOMB® ReNu MultiPlus®
MULTI-PURPOSE SOLUTION

1. Submitter Information

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, New York 14603-0450

Contact Person: Paul G. Stapleton
Director, Regulatory Affairs

Telephone Number: 585-338-8172

2. Device Name

Classification Name: Soft (hydrophilic) Contact Lens Care Solution

Proprietary Name: BAUSCH & LOMB ReNu MultiPlus Multi-Purpose Solution

3. Predicate Devices

Alcon OPTI-FREE EXPRESS has been selected as the predicate device for Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution

4. Description of the Device

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is a sterile, isotonic solution that contains HYDRANATE® (hydroxyalkyl phosphonate) as a protein deposit remover, poloxamine as a surface active agent and salts as tonicity and buffering agents; preserved with DYMED® (polyaminopropyl biguanide) 0.0001%. The product is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner. The sterile solution is contained in a plastic bottle and is labeled with a lot number and expiration date.

5. Indications for Use

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution is indicated for use in the daily cleaning, removing protein deposits, rinsing, chemical (not heat) and storage of soft (hydrophilic) lenses as recommended by your eye care practitioner.

6. Description of Safety and Substantial Equivalence

A series of preclinical and clinical studies were completed on this product and have previously been submitted under Premarket Approval Application P860023/S012, K974723, K002823 and K011796. No concerns were raised for these studies at the time of clearance.

In addition, the following studies have been completed:

Clinical Studies
A multi-site randomized, controlled clinical study was conducted to evaluate the safety and efficacy of ReNu MultiPlus solution when used with a 5 second cleaning rinse prior to the disinfection cycle; no post-disinfection rinse was required. The Control solution was Alcon OPTI-FREE EXPRESS Multi-Purpose Disinfecting Solution No Rub which employed a 5 second cleaning rinse per side both before and after disinfection. Both regimens demonstrated clinically acceptable lens cleanliness. Safety and efficacy were demonstrated.

ReNu MultiPlus Multi-Purpose Solution is substantially equivalent to Alcon OPTI-FREE EXPRESS No Rub.

Substantial Equivalence

Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution for use in a no rub regimen for lenses is substantially equivalent to Alcon OPTI-FREE EXPRESS No Rub.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2002

Mr. Paul G. Stapleton
Director, Global Regulatory Affairs
BAUSCH & LOMB
1400 N Goodman Street
P.O. Box 30450
Rochester, NY 14603-0450

Re: K020802
Trade/Device Name: Bausch & Lomb® ReNu MultiPlus® Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LYL
Dated: March 11, 2002
Received: March 12, 2002

Dear Mr. Stapleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14603-0450

Indications for Use Statement

510(k) Number (if known): K020802

Device Name: Bausch & Lomb® ReNu MultiPlus® Multi-Purpose Solution

Indications for Use:
ReNu MultiPlus Multi-Purpose Solution is indicated for use in daily cleaning, removing protein deposits, rinsing, chemical (not heat) disinfection and storage of soft (hydrophilic) contact lenses as recommended by your eye care practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use ✓

JS

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devices

510(k) Number K020802